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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/727,511 | 12/05/2003 | Juha Voipio | 3501-1077 | 7857 |
| 466 | 7590 | 03/15/2006 | EXAMINER | |
| YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202 | | | MALAMUD, DEBORAH LESLIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3766 | |

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,511

Applicant(s)

VOIPIO ET AL.

Examiner

Deborah Malamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5, 8-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Renirie et al (U.S. 6,141,590). Regarding claims 1 and 8, Renirie discloses (column 3, lines 56-64) “a system for respiration-modulated pacing, providing rate control for controlling the rate of generating and delivering stimulus pulses to correspond to the sensed inspiration and expiration phases of the patient's respiratory cycle. A respiration sensor obtains respiration signals representative of the amplitude and timing of patient respiration, which are used for developing rate modulation signals for controlling delivery of stimulus pulses.” The stimulus pulses (column 4, lines 6-8) “may be delivered to the vagus nerve, or parasympathetic nervous system during expiratory phases, to produce a relative decrease of cardiac rate during expiration phases.” The examiner considers this to be monitoring at least one respirator parameter that correlates to the VNS intensity and regulating the stimulation intensity in response to the parameter.

Regarding claims 2 and 9, Renirie discloses (column 7, lines 23-25) “the respiration sensor (34) provides signals which are processed at (35) to produce

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representations both of the amplitude of the respiration signal and the onset of respiration.”

Regarding claims 5 and 12, Renirie discloses (column 3, lines 48-51) “a system and method for stimulating a patient so as to provide cardiac rate modulation corresponding to a normal respiratory sinus arrhythmia, i.e., respiratory phasic rate variation.” The examiner considers this to teach monitoring respiratory frequency (RF).

3. Claims 1, 3, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al (U.S. 5,199,428). Obel discloses (column 3, lines 15-25) a method to “ameliorate myocardial ischemia and maintain adequate cardiac rate through stimulation of the vagal nervous system (or other effective nerves) as well as the heart tissue in a concerted fashion dependent upon need as automatically determined by the system.” This is accomplished by “comparison of the patient’s coronary sinus blood pH and/or oxygen saturation and/or electrocardiogram ST elevation to preset, normal threshold and triggering burst stimulation of the nerves until the blood gas and/or ST segment variations have been returned to non-clinical risk levels.” The examiner considers this to teach monitoring at least one physiological acid-base parameters which correlate to VNS intensity, and regulating the stimulation intensity in response to the parameter. The physiological acid-base parameter is pH.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4, 6-7, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renirie et al (U.S. 6,141,590). Regarding claims 4, 7 and 11, Renirie teaches the claimed invention except for the measurement of end-tidal carbon dioxide. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the respiration parameter that is measured as taught by Renirie, with the end-tidal carbon dioxide level, because the applicant has not disclosed the end-tidal carbon dioxide detection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the respiratory rate and respiratory amplitude detection as taught by Renirie, because both of these respiratory parameters are representative of the effect of pacing of the vagus nerve. Therefore, it would have been an obvious matter of design choice to modify Renirie's vagus nerve pacing and detection system to obtain the invention as specified in the claims.

Regarding claims 6 and 13, Renirie discloses the claimed invention but does not disclose expressly the use of a capnograph. It would have been an

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obvious matter of design choice to a person of ordinary skill in the art to modify the respiration parameter monitoring as taught by Renirie, with the capnograph, because the applicant has not disclosed the capnograph provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with respiratory sensor as taught by Renirie, because the respiratory sensor is able to detect the respiratory parameters needed to adjust the pacing of the vagus nerve. Therefore, it would have been an obvious matter of design choice to modify Renirie's respiratory sensor to obtain the invention as specified in the claims.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

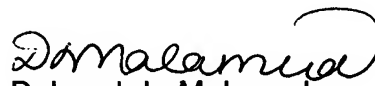
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766



Deborah L. Malamud
Patent Examiner
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